

REMARKS

This paper is filed concurrently with a Request for Continued Examination (RCE).

Claims 38, 40–48, 54–56, 59, 60, and 71–76 are currently in the case. Claims 74–76 are new independent claims.

The previous office action of May 20, 2011 rejected the claims as allegedly obvious over U.S. Patent Nos. 6,340,475 to Shell et al. (“Shell”) and 6,387,403 to Seroff et al. (“Seroff”). This rejection was maintained in an advisory action issued October 3, 2011. Applicants herewith submit a new argument to overcome the previous obviousness rejections in this case. Applicants respectfully ask for reconsideration and withdrawal of the previous rejections in view of the amendments and arguments set forth below, and for allowance of the latest claims.

Interview

The Applicant thanks the Examiner for her time and consideration in speaking with Mark Cohen, the attorney in this matter, on October 18, 2011. The Examiner reiterated and maintained her rejections previously made. She stated her view the current invention was an osmotic device that is obvious over Shell in view of Seroff. She further stated that the fact that Seroff had distinct compartments, and the maltodextrin was in a different compartment than the drug, was inapposite to the obvious analysis.

Claim Amendments

The previous claims have been slightly amended to better clarify the invention.

New Claims

Claims 74–76 are new independent claims. No new matter is added. Claims 74 and 75 have the same limitations of claim 38, but recite narrower ranges of the ratio of water insoluble or partially water insoluble cellulose to maltodextrin. Also, claims 74 and 75 incorporate the

subject matter of claim 46. Claim 76 is directed to a method of providing a sustained release of a pharmaceutical active ingredient in a solid oral dosage form, wherein the water insoluble or partially water insoluble cellulose in combination with maltodextrin controls the release rate of the drug. Claim 76 is supported in the disclosure at paragraph 0024.

Obviousness Rejections

Background

The previous claims stand rejected as allegedly obvious over Shell and Seroff.

Applicants respectfully traverse this rejection.

To briefly reiterate the basis of this invention, the pharmaceutical compositions provided herein have four essential components:

1. A drug (active pharmaceutical ingredient);
2. a sustained (or control) release carrier;
3. a water insoluble or partially water insoluble cellulose; and
4. maltodextrin.

The control release carriers are discussed in detail at paragraph 0040 and retard the release of drug from the composition in aqueous solution or in the digestive tract of a patient (see also paragraph 0004).

The water insoluble or partially water insoluble cellulose are discussed in detail in paragraph 0044, and serve as tableting excipients, that enhance the ability to form tablets of suitable hardness, and preventing tablet disintegration, tears, or holes during manufacture. Preferred water insoluble or partially water insoluble celluloses for use in this invention are starch, microcrystalline cellulose (MCC), and silicified microcrystalline cellulose (SMCC).

As noted in the specification at paragraph 0046, the combination of drug, sustained release carrier, and water insoluble or partially water insoluble cellulose was difficult to formulate while still providing a desired drug release profile. The instant application solves these problems with the addition of maltodextrin to the composition. Significantly, the inventive compositions are homogenous.

The Examiner's obvious argument relies largely on water swellable polymers, which is not a relevant consideration in this case. Applicants concede that hydroxypropyl methylcellulose (HPMC) is a preferred sustained release carrier in the instant invention, and is known to be water swellable, and Applicants further concede the MCC and SMCC, which are preferred water insoluble or partially water insoluble celluloses, may also be water swellable. However, in the instant invention, the control release effect does not depend on the swellability of the polymers, which is the case with Shell and Seroff.

Shell discloses oral dosage forms of drugs by incorporating them into polymeric matrixes comprised of hydrophilic polymers that swell on imbibition of water. However, Shell does not disclose the use of a water insoluble or partially water insoluble cellulose as a tableting excipient in **combination** with the sustained release carrier. Furthermore, as the Examiner concedes, Shell does not disclose the use of maltodextrin.

The Examiner then relies on Seroff, which teaches that maltodextrin is an "osmagent," (osmotically active agent) to allegedly disclose the complete invention.

New Argument

The Applicants respectfully contend that the Examiner has not made a *prima facie* case of obviousness. A *prima facie* case of obviousness must encompass each element of the claimed invention. This flows from the second Graham factor, ascertaining the difference between the

prior art and the claimed invention. *Tokai Corp. v. Easton Enterprises, Inc.*, No. 2010-1057 (Fed. Cir. 1/31/2011), slip op. at 6–7. Shell does **not** disclose **both** the water insoluble or partially water insoluble cellulose and sustained release carrier in the same composition, which is a necessary leg of the Examiner’s previous obviousness arguments. Thus, claim 1 in Shell refers to a **single** polymeric matrix. Example 10, at col. 17 of Shell, uses only polyethylene oxide (a water swellable polymer), in the core of the formulation (although concededly this example includes a coating that contains a small amount of HPMC). The Examiner then relies on Seroff, disclosing the use of maltodextrin in an osmotic pump device, to allegedly provide all four of the claim elements of the instant invention. However, in view of the fact that Shell does not disclose two allegedly water swellable polymers, the combination of Shell with Seroff **does not** encompass each element of the claimed invention.

Furthermore, Shell alone cannot support a *prima facie* obviousness argument, because, as the Examiner concedes, Shell does not disclose the use of maltodextrin in the formulation.

Seroff alone cannot support a *prima facie* case of obviousness or anticipation, because Seroff does not disclose a homogenous mixture of a water insoluble or partially water insoluble cellulose and maltodextrin. Seroff discloses formulations containing maltodextrin, HPMC, and other cellulosic polymers (see for example, examples 4A-4D), but the maltodextrin is not mixed with any of the cellulose polymers. Seroff discloses osmotic pump devices that rely on the imbibition of water and water-swellability of the “osmagents” therein to control the release profile of the drug, which is not a factor in the instant invention.

However, to support a case of anticipation, the prior art elements must be arranged as in the claim. *Therasense, Inc. v. Becton, Dickinson Co.*, 593 F.3d 1325, 1332 (Fed. Cir. 2010). “[C]laims cannot be treated as mere catalogs of separate parts, in disregard of the part-to-part

relationships set forth in the claims and that give the claims their meaning.” *Id.*, internal punctuation omitted. Because Seroff does not disclose a homogenous mass of drug, controlled release carrier, water insoluble or partially water insoluble cellulose and maltodextrin, it is not anticipatory. Nor does Seroff render the instant claims obvious because Seroff teaches the criticality of swellability that is not a factor in the instant invention.

To the extent that functional features of this analysis are relevant, the instant invention does not rely on water-swellability to achieve the control release effect. Rather, the inventor here has found that maltodextrin counteracts the increase in the rate of the release of the drug caused by the water insoluble or partially water insoluble cellulose, for example SMCC. Paragraph 0048. The water-swellability of the sustained release carrier is not a limiting factor, as with Shell and Seroff. This point is amplified by the attached declaration of Nirmal Mulye.

Applicants therefore submit that neither Shell, Seroff, or the combination of Shell and Seroff provide a prima facie case of obviousness, and respectfully request that the rejections be withdrawn.

Pursuant to the rejection of Claim 48 and 67-70, the Office Action cites Shell et al., Seroff et al. and Tobyn et al.

Applicant reiterates the comments hereinabove with respect to and Shell et al. and Seroff et al., the contents of which are incorporated by reference.

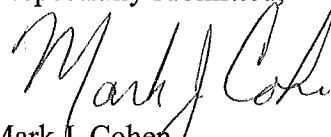
The Office Action is citing Tobyn et al. for the alleged substitution or equivalence of SMCC for microcrystalline cellulose.

Tobyn et al. do not address the inadequacies of Shell et al. and Seroff et al. It merely discloses that there is no discernable chemical or polymorphic difference between microcrystalline cellulose and silicified microcrystalline cellulose. Thus, the above arguments

with respect to the previous rejection are equally as applicable in their entirety. Therefore, this rejection is overcome for the reasons provided; withdrawal thereof is respectfully requested.

Thus, in view of the Amendments to the claims, and the Remarks herein, it is respectfully submitted that the present case is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mark J. Cohen". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

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